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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RODRIGO E. TEIXEIRA

Appeal 2016-003004
Application 12/640,278
Technology Center 1600

Before RICHARD M. LEBOVITZ, JEFFREY N. FREDMAN, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal involves claims to a "method for monitoring cardiac output and/or left ventricular stroke volume of a subject using data obtained from . . . a pulse oximeter," as recited in claim 13. The Examiner rejected the claims as ineligible subject matter under 35 U.S.C. § 101 and as obvious under 35 U.S.C. § 103. We have jurisdiction under 35 U.S.C. § 134.

We affirm.

Appellant appeals from the Examiner's final rejection (May 14, 2015) ("Final Rej.") of claims 13, 15–18, 23, 24, 31, and 40–42. The claims stand rejected by the Examiner as follows:

1. Claims 13, 15–18, 23, 24, 31, and 40–42 under 35 U.S.C. § 101 as being drawn to non-patentable subject matter. Final Rej. 2.

2. Claims 13, 15–18, 23, 24, 31, and 40–42 under 35 U.S.C. § 103(a) as obvious in view of Feldman (US 5,626,140, patented May 6, 1997), Tax (David M.J. Tax et al., *Combining multiple classifiers by averaging or by multiplying?*, Pattern Recognition, 2000, 33, 1475–85 (2000)), Natalini (Guiseppe Natalini et al., *Arterial Versus Plethysmographic Dynamic Indices to Test Responsiveness for Testing Fluid Administration in Hypotensive Patients: A Clinical Trial*, Anesth. Analg. 103, 1478–84 (2006)) and Awad (Aymen A. Awad et al., *Analysis of the Ear Pulse Oximeter Waveform*, J. Clinical Monitoring and Computing, 20, 175–84 (2006)). Final Rej. 6.

Claim 13, the only independent claim on appeal, reads as follows:

> 13. A method for monitoring cardiac output and/or left ventricular stroke volume of a subject using data obtained from said subject by a pulse oximeter, said method comprising:
>
> a) entering, in a data processor, state and model parameters for a time t into a dynamic state-space model to produce a first probability distribution function vector comprising state and model parameters for time t+n;
>
> b) entering timed data for time t+n obtained from said biomedical monitoring device into said data processor;
>
> c) producing a second probability distribution function vector using said data processor for state and model parameters for time t+n in a Bayesian statistical process using the first probability distribution function vector and the timed data obtained for time t+n;

> d) calculating probabilistic expectation values for the state and model parameters for time t+n from the second probability distribution function using said data processor;
>
> e) determining an estimated value for cardiac output and/or left ventricular stroke volume for time t+n from probabilistic expectation values for the state and/or model parameters for time t+n; using said data processor and
>
> f) reporting the estimated value for cardiac output and/or left ventricular stroke volume for time t+n
>
> wherein:
>
> the dynamic state-space model mathematically represents the cardiovascular system of the subject to produce a time dependent state representing a time dependent physiological state of the cardiovascular system of the subject;
>
> the state and model parameters for a time t entered into the dynamic state-space model in step a) are in the form of a probability distribution function produced from a sampling of expectation values calculated in step c) for an immediately preceding time t-n'; and
>
> n and n' are time intervals that may be the same or different.

Appeal Br. 19 (Claims App.).

SECTION 101 REJECTION

To determine whether a claim is eligible for patent under 35 U.S.C. § 101, a two-step analysis is necessary. As set forth in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S.Ct. 2347, 2355 (2014):

> First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts [*e.g.,* a law of nature, natural phenomenon, or abstract idea]. If so, we then ask, what else is there in the claims before us? . . . We have described step two of this analysis as a search for an inventive concept—*i.e.*, an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.

Id. (alterations, citations, and quotation marks omitted).

Under the first step, it must be determined if the process of claim 13 is a law of nature, natural phenomenon, or abstract idea. According to the Examiner, the claimed method is an abstract idea because it "describes the concept of gathering and combining data by reciting steps of organizing information through mathematical relationships to manipulate existing information to generate additional information" in order to "mathematically represent physiological processes involved in generating physiological parameters measured by a biomedical sensor." Final Rej. 2–3.

The Examiner's findings are supported by the plain steps of the claim. The claimed method involves obtaining data from a pulse oximeter, and then, using a data processor, determining the mathematical relationships between the data and the values for cardiac output and/or stroke volume to represent the physiological state of the cardiovascular system of the subject. The method therefore involves determining the relationship between pulse oximeter data and the cardiovascular system which is an abstract idea, i.e., it is a non-physical, computer ("data processor") representation of the relationship between pulse oximeter data and cardiac output and stroke volume. A claim that merely describes a relation that is a consequence of natural processes, namely, physiological data collected from a pulse oximeter sensor and its relationship to the cardiovascular system, is ineligible for a patent because it is a natural law. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289 (2012). For these reasons, we conclude claim 13 is directed to patent ineligible subject matter under the first part of the *Alice* test.

The second step of the analysis requires a determination of whether the claims do significantly more than simply describe the abstract idea or

natural law. *Mayo*, 132 S.Ct. at 1297. The claim limitations must be scrutinized to determine whether the claims contain an "inventive concept" to "transform" the claimed abstract idea or natural law into patent-eligible subject matter. *Alice*, 134 S.Ct. at 2357 (*quoting Mayo*, 132 S.Ct. at 1294, 1298).

> The transformation of an abstract idea into patent-eligible subject matter "requires more than simply stat[ing] the [abstract idea] while adding the words 'apply it.' " *Id.* (quoting *Mayo*, 132 S.Ct. at 1294) (alterations in original). "A claim that recites an abstract idea must include 'additional feature' to ensure 'that the [claim] is more than a drafting effort designed to monopolize the [abstract idea].' " *Id.* (quoting *Mayo*, 132 S.Ct. at 1297) (alterations in original). Those "additional features" must be more than "well-understood, routine, conventional activity." *Mayo*, 132 S.Ct. at 1298.

Ultramercial, Inc. v. Hulu, LLC, 772 F.3d 709, 715 (Fed. Cir. 2014).

In this case, claim 13 simply instructs the practitioner to implement the abstract idea using routine, conventional activity. The recited steps involve entering data into a data processor, calculating probability distributions, and using that information to determine an estimated value of cardiac output or left ventricular stroke volume. The claim requires "reporting" the estimated values, but does not describe how the reporting is accomplished. The steps of the claims do not appear to add anything significantly more to the ineligible idea and natural law. Rather, they constitute "routine, conventional activity" utilized to model physiological data. Appellant has not provided persuasive evidence to the contrary to rebut the Examiner's findings.

Appellant contends that the Examiner erred in determining that the claim is ineligible for a patent under Section 101 because "the published application disclose[s] that the claimed method enables the extraction of

cardiac output and/or left ventricular stroke volume from pulse oximetry data, which is clearly an improvement in the technical field of noninvasive measurement of cardiac output." Reply Br. 5. Appellant argues that "[t]he fact that the method involves a complex mathematical algorithm including a dynamic state space model does not, in and of itself, cause the claimed method to fall under a judicial exception to patentability under 35 U.S.C. 101." *Id.*

We do not agree. In *Mayo*, the Court concluded that "the claims were necessarily directed to an underlying law of nature or natural phenomenon, even if implementation of the method involves substantial human labor and ingenuity." *Genetic Technologies Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1375 (Fed. Cir. 2016). Thus, even if Appellant made an improvement in the measurement of noninvasive cardiac output, such "ingenuity" does not confer patent eligibility under Section 101 because the first step under *Alice* is whether the claim is an abstract idea or natural law, not whether it requires originality or creativity to derive and discover it. The fact that is may be a better method also does not confer patentability. *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1371 (Fed. Cir. 2011).

Appellant argues that "[t]he *'solution'* of estimating values for cardiac output and/or stroke volume is therefore inseparable from the data input from the pulse oximeter so entering of data from the pulse oximeter cannot reasonably be considered as an *'insignificant extra-solution activity.*'" Reply Br. 5. This argument does not persuade us that the Examiner erred. The entry of data into a data processor as required by claim 13 is a routine and conventional step. *Mayo* explicitly held that the "[t]hose 'additional features' [recited in the claimed method] must be more than 'well-

understood, routine, conventional activity.'" *Mayo*, 132 S.Ct. at 1298. Appellant has not directed us to a step in the claim which is unconventional and adds significantly more to the abstract relationship between physiological data and cardiac output or stroke volume embodied by the claim.

Appellant cites *Ex parte Poisson,* No. 2012-011084 (PTAB Feb. 27, 2015), which he contends demands reversal of the Examiner's rejection. Appeal Br. 6.

First, we note that *Poisson* is not a precedential decision and therefore we are not bound by it.

Second, we have reviewed *Poisson* and do not consider it to be pertinent to the issue in this appeal. In *Poisson*, the Patent Trial and Appeal Board ("Board") rejected the Examiner's conclusion that the claims were directed to an abstract idea of a new set of rules for playing a card game. *Poisson* 5. Instead, the Board found that the claim involved playing a game of football "using a table and cards." *Id.* The Board reversed the Examiner's rejection because the Examiner did not provide adequate findings of fact "on which to base the *Alice* analysis." *Id.* Thus, the Board concluded that the facts and evidence relied upon by the Examiner did not support a finding that the claim was an ineligible abstract idea. *Id.* Here, the Examiner made adequate findings of fact, as discussed above, that the claimed method is an abstract idea. Appellant does not identify a defect in the Examiner's fact-finding, but rather argues the conclusion is wrong.

With respect to claims 23 and 24, which are directed to a data processor and pulse oximeter configured to perform the method of claim 13, the Examiner stated that the additional limitations were generic hardware

and devices which do not transform the abstract idea into eligible subject matter. Final Rej. 4. We agree. The additional recitation that the method is performed with a configured pulse oximeter and configured data processor adds the conventional devices on which measurements are gathered and calculations are performed, and does not disguise the claim from being what it is – an abstract idea and expression of a natural law.

In sum, we affirm the rejection of claims 13, 15–18, 23, 24, 31, and 40–42 under § 101.

OBVIOUSNESS REJECTION

Feldman teaches obtaining data from sensors to get "the best estimate of heart rate at any point in time." Feldman, col. 3, ll. 36–45. The Examiner found that Feldman applied a Kalman filter to the sensor data as a probability density function. Final Rej. 6 (see step a of claim 13 of entering data "to produce a first probability distribution function vector comprising state and model parameters for time t+n"). In the next stage of data analysis, the Examiner found that Feldman taught applying Bayesian statistics to determine posterior probabilities. *Id.*, 7 (see step c of claim 13 of "producing a second probability distribution function vector using said data processor for state and model parameters for time t+n in a Bayesian statistical process using the first probability distribution function vector"). *See also* Ans. 4 ("To this end, Feldman is viewed as teaching the method as claimed of obtaining first probability distribution using state-space model (Kalman filter), and then, using Baysesian [sic, Bayesian] statistical process, obtaining second probability distribution function to determine changes in the model parameter (e. g., heart rate) over time.").

The Examiner found that heart rate was described as an example of a physiological parameter in Feldman (at col. 11, l. 40), providing a reason to apply the Feldman model to other physiological parameters of interest. Final Rej. 7. The Examiner further found that Awad and Natalini described utilizing pulse oximeter data to predict cardiac output changes, the same parameter which is claimed. *Id.*, 8. Based on these teachings the Examiner determined "it would be obvious to one skilled in the art that if changes in cardiac output (or stroke volume) are of interest as a physiological model parameter, it can be predicted from plethysmography data provided by pulse oximeter." *Id.*

The Examiner further cited Tax for the advantages of using vectors in Bayesian analysis. *Id.* The Examiner states that it would have been obvious to one of ordinary skill in the art "to present data in mathematical modeling of sensor data in Feldman in vector form [steps (a) and (c) of the claimed method refer to probability distribution function vectors], as the vector form is a common way of data presentation in mathematical analysis as exemplified by [Tax]." *Id.*, 9.

Appellant contends that the rejection does not address the first probability function vector comprising state and model parameters for time t+n. Appeal Br. 10–11. We do not agree.

The Examiner found:

> In Feldman, the parameter variability statistical model characterizes changes in the parameter over time (i.e., using the language of the instant claims, times *t, t+n, t+n+m).* See Feldman, claims 13, 16, 20, 26, 29, 33. From probabilistic expectation values, and estimated value for the physiological parameter is then determined. See Abstract, end; claim 1, end.

Final Rej. 7. Appellant does not identify an error in the Examiner's findings.

Appellant also argues:

> The Examiner appears to imply that Feldman's sensor data is equivalent to state parameters and that Feldman's physiological parameter is equivalent to a model parameter. This is incorrect because the terms "state parameter" and "model parameter" recited in the rejected claims only have meaning in the context of a DSSM [dynamic state-space model] and the DSSM recited in the present claims must comprise a mathematical model representing physiological processes the produce cardiac output and/or left ventricular stroke volume.

Appeal Br. 11.

This argument does not persuade us that the Examiner erred. The Specification teaches that "[t]he computational model includes variable state parameter output data that corresponds to a physiological parameter being measured to mathematically represent a current physiological state for a subject." Spec. 4: 1–3 (emphasis added). The Specification also teaches that "[t]he estimated value of the physiological parameter being measured (estimated) may also correspond directly to (*i.e.* be equal to) the value of the model parameter." *Id.*, 4: 7–9. Such disclosure provides adequate evidence that the Examiner's findings concerning state and model parameters are correct.

Appellant does not provide evidence to the contrary, but merely states that such parameters "only have meaning in the content of a DSSM." Appeal Br. 11. This argument fails to identify a difference between the steps of claim 1 and the steps in the computational model described by Feldman. Appellant's generic reference to DSSM in their arguments does not clarify how the steps of the DSSM model as recited in the claims are

distinguishable from the steps of Feldman, and Feldman in view of Natalini, Awad, and Tax. Appellant contends that Feldman does not teach or suggest DSSM, but fails to specifically identify what step of the claimed method is missing. *Id.*, 11–12.

Similarly, in the Reply Brief, Appellant attempts to distinguish the Kalman filter step in Feldman from the DSSM model. Reply Br. 8. However, the Examiner did not rely solely on the Kalman filter described in Feldman, but the Examiner also relied on the teaching of Bayesian steps. *See above*, pp. 8–9. Appellant repeatedly refers to what the Specification describes as DSSM (Reply Br. 8–10), but does not identify how this description adds meaning to the steps in the recited claim, or how the claim is distinguished from Feldman. The claim is being examined for what Applicant regards as the invention ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. 112, second paragraph), not the written description of the Specification.

Appellant states that Awad reinforces a need for methods to measure cardiac output. Appeal Br. 14. Appellant contends that Awad is deficient. Appellant argues:

> Awad discloses that a correlation between changes in CO [cardiac output] and ear plethysmographic waveforms was found by using multi-linear least squares regression (abstract). Awad, at the left-hand column of page 183 explicitly states that that the significant correlation "is not adequate to develop a new method of reliably predicting cardiac output" and that Awad is "not claiming that we have a non-invasive device to measure CO."

Id.

Awad found that the ear plethysmographic width "had a significant correlation with the HR [heart rate] and CO." Awad, Abstract. The Examiner relied upon this fact to find that it would be predictable to determine a relationship between ear plethysmographic data and CO. Final Rej. 8. Appellant does not demonstrate an error in this finding. Instead, Appellant points out that Awad's model did not reliably predict cardiac output and that "that pulse oximetry cannot be used to measure or predict cardiac output." Reply Br. 10. However, the Examiner did not rely on Awad for the model. Final Rej. 6–8. Rather, the Examiner relied upon Awad for its teaching of a correlation between CO and plethysmographic data, providing a factual basis to apply Feldman's model to it with a reasonable expectation of success.

Appellant states that the rejection of claims 23, 24, and 40 should be reversed at least for the same reasons as claim 13. Appeal Br. 15–16. Because we find the arguments for claim 13 unpersuasive, we affirm the rejection of claims 23, 24, and 40 for the same reasons.

Appellant states that the Examiner did not address the limitations in claim 31. *Id.*, 16. With regard to claim 31, the Examiner stated that "any differences between . . . claimed method and that of the prior art, the differences would be appear minor in nature. The claims contain either additional features known *per se* from the prior art or being slight constructional changes which come within the scope of the customary practice followed by the persons skilled in the art." Final Rej. 9. Appellant does not identify a step in claim 31 which is not a prior art customary practice.

For the foregoing reasons, we affirm the obviousness rejection of claims 13, 23, 24, and 31. Dependent claims 15–18 and 40–42 are not argued separately and therefore fall with claims 13, 23, 24, and 31.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED